

§ 20.21

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(3) The disclosure is one that is discretionary, i.e., not required under this part.

(e) “Record” and any other term used in this section in reference to information includes any information that would be an agency record subject to the requirements of this part when maintained by the agency in any format, including an electronic format.

[42 FR 15616, Mar. 22, 1977, as amended at 68 FR 25285, May 12, 2003]

§ 20.21 Uniform access to records.

Any record of the Food and Drug Administration that is disclosed in an authorized manner to any member of the public is available for disclosure to all members of the public, except that:

(a) Data and information subject to the exemptions established in § 20.61 for trade secrets and confidential commercial or financial information, and in § 20.63 for personal privacy, shall be disclosed only to the persons for the protection of whom these exemptions exist.

(b) The limited disclosure of records permitted in § 7.87(c) of this chapter for section 305 hearing records, in § 20.80(b) regarding certain limitations on exemptions, in § 20.103(b) for certain correspondence, and in § 20.104(b) for certain summaries of oral discussions, shall be subject to the special rules stated therein.

(c) Disclosure of a record about an individual, as defined in § 21.3(a) of this chapter, that is retrieved by the individual’s name or other personal identifier and is contained in a Privacy Act Record System, as defined in § 21.3(c) of this chapter, shall be subject to the special requirements of part 21 of this chapter. Disclosure of such a record to an individual who is the subject of the record does not invoke the rule established in this section that such records shall be made available for disclosure to all members of the public.

[42 FR 15616, Mar. 22, 1977, as amended at 54 FR 9037, Mar. 3, 1989]

§ 20.22 Partial disclosure of records.

(a) If a record contains both disclosable and nondisclosable information, the nondisclosable information will be deleted and the remaining

record will be disclosed unless the two are so inextricably intertwined that it is not feasible to separate them or release of the disclosable information would compromise or impinge upon the nondisclosable portion of the record.

(b)(1) Whenever information is deleted from a record that contains both disclosable and nondisclosable information, the amount of information deleted shall be indicated on the portion of the record that is made available, unless including that indication would harm an interest protected by an exemption under the Freedom of Information Act.

(2) When technically feasible, the amount of information deleted shall be indicated at the place in the record where the deletion is made.

[42 FR 15616, Mar. 22, 1977, as amended at 68 FR 25285, May 12, 2003]

§ 20.23 Request for existing records.

(a) Any written request to the Food and Drug Administration for existing records not prepared for routine distribution to the public shall be deemed to be a request for records pursuant to the Freedom of Information Act, whether or not the Freedom of Information Act is mentioned in the request, and shall be governed by the provisions of this part.

(b) Records or documents prepared by the Food and Drug Administration for routine public distribution, e.g., pamphlets, speeches, and educational materials, shall be furnished free of charge upon request as long as the supply lasts. The provisions of this part shall not be applicable to such requests except when the supply of such material is exhausted and it is necessary to reproduce individual copies upon specific request.

(c) All existing Food and Drug Administration records are subject to routine destruction according to standard record retention schedules.

§ 20.24 Preparation of new records.

(a) The Freedom of Information Act and the provisions of this part apply only to existing records that are reasonably described in a request filed with the Food and Drug Administration pursuant to the procedures established in subpart C of this part.